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510(k) Summary

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Omron Healthcare, Inc.
1200 Lakeside Dr.
Bannockburn, IL 60015

Tel – 847-247-5713
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Official Contact: Donna Djinovich – Regulatory Affairs Manager

Proprietary or Trade Name: Omron Compressor Systems

Common/Usual Name: Nebulizer Compressor Systems

Classification Name: Nebulizer (Direct Patient Interface)

Device: Models NE-C28 and NE-C30

Predicate Devices: Omron – NE-C09 – K914836

Device Description:

The Omron Compressor Systems, model NE-C28 and NE-C30, consist of a nebulizer and AC powered piston-type compressor that's generates compressed air. The Model NE-C30 also includes a rechargeable battery pack and can be connected to DC voltage.

Both units utilize the same handheld nebulizer, which is a venturi type which converts the liquid medication into a fine aerosol which is inhaled by the patient via a mouthpiece of mask. The nebulizers can be cleaned and reused.

Indications for Use:

Indicated Use -- The Omron Compressor Nebulizer Systems include a compressor and nebulizer, Model NE-C28 uses a DC powered compressor and Model NE-C30 can operate with AC/DC power. The electrically powered compressor provides compressed air to the supplied pneumatic nebulizer to aerosolize drugs for inhalation by the patient.

The nebulizer is driven by the integral air compressor. The device may be used with pediatric and adult patients in the home, hospital, and sub-acute care settings.

Not intended for use with Pentamidine.

Patient Population -- Pediatric and adult

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Environment of Use -- Home, hospital, and sub-acute care settings.

Contraindications -- None

Device Attributes:

Features	NE-C28	NE-C30
Indications for use	The electrically powered compressor provides compressed air to the supplied pneumatic nebulizer to aerosolize drugs for inhalation by the patient. The nebulizer is driven by the integral air compressor.	Same
Environment of Use	Home, Hospital, Sub-acute Institutions	Same
Patient Population	Pediatric and adult	Same
Contraindications	None	Same
Pneumatic compressor	Yes	Yes
Pneumatic nebulizer	Yes	Yes
Software driven	No	No
Materials in patient contact	Polypropylene	Identical
Standard met	IEC 60601-1, IEC 60601-1-2, UL 60601-1, FCC Part 15 ISO 14971	Same
Drug delivery rate	0.35 ml/min	0.4 ml/min
Reservoir size	7 ml	7 ml
Nebulizer components cleanable	Yes	Yes
Operating conditions	10°C to 40°C 30% to 85% RH	Same
Storage conditions	-20°C to 60°C 10% to 90% RH	Same
Dimensions (mm)	168(W) x 175(D) x 100(H)	124(W) x 98(D) x 51(H)
Weight (kg) without battery	1.7 kg	0.4 kg

Differences Between Other Legally Marketed Predicate Devices

The Models NE-C28 and NE-C30 are viewed as substantially equivalent to the following predicate device – Omron NE-C09 – K914836.

There are no significant differences that affect the safety or effectiveness of the intended device as compared to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 25 2006

Omron Healthcare, Incorporated
C/O Mr. Paul Dryden
President
ProMedic, Incorporated
6329 West Waterview Court
Mccordsville, Indiana 46055-9501

Re: K060811
Trade/Device Name: Omron Compressor Systems, Models NE-C28 and NE-C30
Regulation Number: 868.5630
Regulation Name: Nebulizer
Regulatory Class: II
Product Code: CAF
Dated: March 23, 2006
Received: March 24 2006

Dear Mr. Dryden:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number: K060811

Device Name: Models NE-C28 and NE-C30

Indications for Use: The Omron Compressor Nebulizer Systems include a compressor and nebulizer, Model NE-C28 uses a DC powered compressor and Model NE-C30 can operate with AC/DC power. The electrically powered compressor provides compressed air to the supplied pneumatic nebulizer to aerosolize drugs for inhalation by the patient.

The nebulizer is driven by the integral air compressor. The device may be used with pediatric and adult patients in the home, hospital, and sub-acute care settings.

It is not intended for use with Pentamidine.

Prescription Use XX (Part 21 CFR 801 Subpart D) **or** **Over-the-counter use __** (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

[illegible] Division of Cardiology, General Hospital, [illegible] Dental Devices

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